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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,962	01/07/2004	Takashi Suzuki	2003_1924A	4501

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WASHINGTON, DC 20006-1021

EXAMINER
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SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
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1657

MAIL DATE	DELIVERY MODE
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06/15/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/751,962	Applicant(s) SUZUKI ET AL.	
	Examiner Dr. Kailash C. Srivastava	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 10-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 10-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

1. Response and amendment filed 21 March 2007 in response to Office Action mailed 21 September 2006 are acknowledged and entered.
2. In view of applicants' remarks filed 21 March 2007, objection to specification in the Office Action mailed 21 September 2006 is hereby withdrawn:
3. Please note, however, that applicants are claiming priority to a document under 35 U.S.C. §119 (a-d) or (f) to a document filed 7 January 2004. Priority to said document has not been properly recited at Page 1, Line 1 of the specification as currently presented.

## CLAIMS STATUS

4. Claims 4-9 have been cancelled.
5. Claims 10-12 have been added.
6. Claims 1-3 have been amended.
7. Claims 1-3 and 10-12 are pending and are examined on merits.

## Claim Rejections - 35 U.S.C. §112

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §112, second paragraph that form the basis for the rejections under this section made in this Office action:

*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.*

9. Claims 1-3 and newly presented Claims 10-12 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In response to rejections made in the Office action mailed 21 September 2006 under 35 U.S.C. §112, second paragraph to Claims 1-3, reciting M.P.E.P. §2173.04 applicants argue that amended claims 1-3 are not indefinite because all the steps for claimed method to produce the claimed product (i.e., yeast extract) have been presented. Applicants also argue that the indefiniteness rejection should not be made in "vacuum, but taking in to consideration the teachings of the specification and the knowledge in the art". Applicants further argue, 'it is well established that breadth of a claim is not to be equated with

indefiniteness so long as the scope of the subject matter embraced by the claims is clear”.

Applicants are right in asserting that the steps for the claimed method to prepare a yeast extract have been presented in the amended Claim 1. The claim 1 as presented is vague and indefinite because merely pressing frozen yeast cells in a mortar pestle assembly will not result in a suspension of broken yeast cell walls and the intracellular material obtained from the breaking process. Art-known procedures for this step clearly teach addition of a buffer that is usually comprises protease inhibitors to preserve the proteases and dithiothreitol to preserve the activity of certain components of the intracellular material that comes out during the breaking process. The extract is a matter that is obtained from another matter through the process of extraction, wherein the extracted material is physically removed from its original harboring place or preparation (e.g., a volatile extract of plant prepared through distillation, wherein the volatile materials of said plant are transferred in to the distillate). In the steps presented in Claim 1, the extracted material, i.e., yeast intracellular materials have not been removed from the suspension comprising frozen cells and buffer in which the cells were broken, rather they merely remain suspended in the buffer. The removed matter are the cell wall debris material and the removed intracellular components of molecular weight no greater than 5,000.

Regarding applicants' arguments that the “indefiniteness of claimed language is not determined in vacuum, but taking in to consideration the teachings of the specification and the knowledge in the art”, please note, the invention is the subject matter defined in the claims, and the limitations of the specification are not read in to the claims where no express statement of that limitation is included in the claims (See *In re Priest*, 199USPQ 11). Regarding equating breadth of the claims with indefiniteness, Claims are unpatentable when they are so broad as to read on obvious subject matter even though they likewise read on non-obvious subject matter. (*In re Mraz*, 173 USPQ 25, 28 (CCPA 1972). In instant case, the method steps as presented in Claim 1 are well known in the art to prepare yeast homogenates or any cell homogenates especially to assay the metabolic pathways/enzyme activities.

10. In view of applicants' amendments filed 21 March 2007, following are new rejections to claims 1-3 and 10-12 under 35 U.S.C. §112, second paragraph.

11. Claims 1-3 and newly presented Claims 10-12 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention

- Claim 1 seems to be incomplete in the absence of a recovery step for the product produced.

While there is no specific rule or statutory requirement which specifically addresses the need for a recovery step in a process of preparing a composition, it is clear from the record and would be expected from conventional preparation processes that the product must be isolated or recovered. Thus, the claims fail to particularly point out and distinctly claim the "complete" process since the recovery step is missing from the claims. The metes and bounds of the claimed process are therefore not clearly established or delineated.

- Claim 10 is unclear by the abbreviations "DTT", "HEPES" and "PMSF". Despite these abbreviations being art-known, abbreviations in the first instance of claims should be expanded upon with the abbreviation indicated in parentheses. The abbreviations can be used thereafter.
- Claim 11 does not further limit claim 10 since the PMSF a protease inhibitor is already mentioned in Claim 10.

All other claims depend directly from the rejected claims (1, 15 or 20) and are, therefore, also rejected under 35 U.S.C. § 112, second paragraph for the reasons set forth.

### ***Claim Rejections – 35 U.S.C. § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

*A person shall be entitled to a patent unless –*

*(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.*

13. Claims 1-3 and newly presented Claims 10-11 are rejected under 35 U.S.C. § 102(b) as anticipated by Schultz (Methods: A comparison to Methods in Enzymology, 1999, Volume 17, Pages 161-172).

In response to rejections made in the Office action mailed 21 September 2006 under 35 U.S.C. § 102(b) to Claims 1-3, as anticipated by Schultz, reciting MPEP applicants argue that said claims are not anticipated by the cited prior art. Applicants further argue, "Schultz fails to disclose or suggest the steps of removing intracellular components having a molecular weight of  $\leq 5,000$  from said extract solution and concentrating the resulting solution to obtain the yeast extract solution capable of cell protein synthesis".

Schultz teaches dialyzing the prepared supernatant obtained post centrifugation in a dialysis tube and flash freezing said dialyzed material. Thus, Shultz teaches concentrating the resulting material post breackage and dialysis to remove materials of molecular weight of  $\leq 5,000$ . Furthermore, Schultz's dialysis solution contains, PMSF (See Table 1 at Page 163, Column 2)), DTT and the buffer is KOH-HEPES (See Page 164, Column 1, Lines 15-20).

Applicants' arguments filed 21 December 2006 regarding the rejection to Claims 1-3 as anticipatory by Schultz (Methods: A comparison to Methods in Enzymology, 1999, Volume 17, Pages 161-172) in the Office Action mailed 21 September 2006 have been fully and carefully considered, but are not persuasive for the reasons:

- (i) discussed *supra*; and
- (ii) of record at pages 2-3, item 6 in the Office Action mailed 21 September 2006.

### CONCLUSION

14. Applicant's amendment (i.e., amendments to Claim 1-3 and addition of Claims 10-12) necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR §1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR §1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


15. For the aforementioned reasons, no claims are allowed. However, Claim 12 is free of art.

16 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
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11 June 2007

  
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